UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STEVEN B. CHRISTIANSEN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. SPECTRUM PHARMACEUTICALS, INC., THOMAS J. RIGA, FRANCOIS J. LEBEL, and NORA E. BRENNAN, Defendants.	Case No. 1:22-cv-10292 (VEC) (Consolidated) Oral Argument Requested

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS

BAKER BOTTS L.L.P.

Kevin M. Sadler (*pro hac vice*)
1001 Page Mill Road
Building One, Suite 200
Palo Alto, California 94304-1007
(650) 739-7500

Scott D. Powers (*pro hac vice*)
401 South 1st Street
Suite 1300
Austin, Texas 78704-1296
(512) 322-2500

James J. Beha II
John B. Lawrence
Eric DuPont
30 Rockefeller Plaza
New York, New York 10112-4498
(212) 408-2500

Counsel for Defendants Spectrum Pharmaceuticals, Inc., Thomas J. Riga, Francois J. Lebel, and Nora E. Brennan

TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Page(s)

CASES

INTRODUCTION

Plaintiff's opposition presents a classic case of misdirection. Rather than explaining why Spectrum's actual statements were false when made, Plaintiff attempts to recharacterize Spectrum's statements so they will now appear false in light of events as they later unfolded. No Defendant ever said "Spectrum was enrolling patients" or that "Defendants had learned to 'optimize' the dosage of pozi." (Pl. Br. at 1.) And the statement about "alignment" between Spectrum and the FDA went to the narrow question of whether it would be preferable to use one 16-mg dose or two 8-mg doses in the confirmatory study.

Plaintiff's claim—filed in the wake of the "all-but-inevitable decline" in a drug company's stock price "following [an] announcement that the FDA ha[s] not approved" the company's new drug application, *Fort Worth Emp'rs Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 229 (S.D.N.Y. 2009)—is the type of fraud-by-hindsight lawsuit the PSLRA was meant to eliminate. The Complaint fails the PSLRA's pleading standards. The opposition confirms this failure.

First, Plaintiff fails to show that any of Spectrum's statements were false or misleading.[1]

> Dosage. Defendants never said they "had learned to 'optimize' the dosage of pozi." (Pl. Br. at 1.) Defendants simply conveyed their belief that a daily 16-mg dose was safe and effective while also noting that a twice-daily 8-mg dose helped "optimize some of the tolerability and abate some of the [adverse events]." The FDA's desire for more data related to dosage does not make Spectrum's statements false.
>
> Alignment on the Confirmatory Study. Mr. Riga told investors he "believed" Spectrum was "obviously aligned with [the] FDA on the confirmatory study to go with 8-milligram BID." While some FDA review team members later criticized the study, the Briefing Book confirms "[Spectrum] and the FDA agreed that the 8 mg BID regimen as the starting dosage was preferable in the confirmatory trial."
>
> Patient Enrollment. Plaintiff argues that statements about the confirmatory study's design falsely suggested Spectrum had begun enrolling patients. Defendants never suggested patients were already enrolled. In fact, when asked, Defendants expressly

---

[1] Attached as Appendix A is a list of each challenged statement in context. References to "Statement No." are to the designations in Appendix A.

declined to address enrollment status. Plaintiff points to a single equity analyst who misunderstood, while ignoring others who understood.

Risk Factors. Spectrum cautioned that failed clinical studies could delay or prevent regulatory approval of its drugs. This accurate risk disclosure was not misleading.

Second, Plaintiff fails to plead scienter. His motive theory—based on de minimis personal stock sales and unremarkable corporate stock sales—fails as a matter of law. His attempt to show recklessness fails, too, because he cannot show how the FDA Briefing Book conflicts with Spectrum's statements. The Court should dismiss the Complaint.

I. THE COMPLAINT FAILS TO ALLEGE FALSITY

The opposition repeatedly asks the Court to ignore the full context of Spectrum's statements. But Plaintiff "may not cherry pick certain public statements for [his] complaint and divorce them from the universe of disclosed information." *In re Synchrony Fin. Secs. Litig.*, 988 F.3d 157, 171 (2d Circ. 2021). The Court must "read[ ] each statement . . . in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 190 (2015). In doing so, the Court "may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents . . . and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit."[2] *In re Synchrony*, 988 F.3d at 171. Plaintiff fails to show that any of Spectrum's statements were false or misleading when considered in context.

A. Dosage Statements (Statements 1, 4, and 5)

Mr. Riga never told investors Spectrum "had learned to optimize the pozi dosage." (Pl. Br. at 4.) In fact, when comparing the two possible dosage regimes (16-milligram QD and 8-

[2] For this reason, the Court can take judicial notice of the Exhibits to the Motion.

milligram BID), he said, "I think over time, we have learned to optimize some of the tolerability and abate some of the [adverse events] here with the BID dosage." (Statement No. 1.) And he did so after describing a study showing "better tolerance and nearly 20% lower dose reductions" with the 8-mg BID dose. (Ex. 24 at 6.) Thus, Mr. Riga's actual statement was accurate, appropriately contextualized, and supported by available data.

Spectrum's other statements about dosage accurately described the company's views while disclosing the existence of ongoing discussion with the FDA. First, on March 17, 2022, an equity research analyst asked about "the potential label" for poziotinib and whether there was "a possibility of getting the 8-milligram BID dosing." (Ex. 24 at 11.) Mr. Riga replied:

> [W]e are seeing that 16 QD is certainly a safe and effective dose. And I think over time, we have learned to optimize some of the tolerability and abate some of the [adverse events] here with the BID dosage. So I think that will be a key topic when we get to label negotiations with the agency, and we're simply not at that point of the review cycle, which will be coming here shortly. (Statement No. 1; Compl. ¶ 123.)

Then, on May 12, 2022, Spectrum disclosed that it had initiated the confirmatory study using an 8-mg BID dosage and disclosed that the FDA planned to hold an ODAC meeting. (Ex. 11 at 4, 6.) An analyst asked what Mr. Riga was "expecting the advisory committee to ask." (Ex. 11 at 8-9.) He replied:

> We're looking forward to the opportunity to bring this to an advisory committee and really share the full benefit that pozi could bring in this high area of unmet need. So if you think about even at the acceptance, we had made some statements that the FDA had questions about the status of the confirmatory study as well as questions on the dose. And today, we announced the PINNACLE study which has a dose of 8-milligrams BID, which is different than the 16-milligram QD registrational data. So it's, for us, very – it makes a lot of sense. It's very logical that the FDA could have additional questions on dosing and wanting to hear from industry experts on how to bring that issue to resolution. But that's us looking at where we've been, what the discussions have been with the agency, those are two of the issues that certainly could be discussed at ODAC. . . (Statement No. 4; Compl. ¶ 130.)

Another analyst asked a follow-up question about the different dosage regimes in the NDA and the confirmatory study. (Ex. 11 at 9.) Mr. Riga answered that:

> We believe that 16-milligrams QD demonstrated a safe and effective dose for a patient population that needs a solution. I think the subsequent data has given an indication that there could be a more optimal way to reduce some of the on-target toxicities. So I think that the conundrum that you mentioned is likely a topic that FDA would like to hear from industry experts at the ODAC panel. But we believe that 16 QD is a safe and effective dose and obviously aligned with FDA on the confirmatory study to go with 8-milligram BID. (Statement No. 5; Compl. ¶ 128.)

In short, the Defendants expressed their belief that the 16-mg QD dose was safe and effective, noted that the 8-mg BID dose might "be [] more optimal," and disclosed that "the FDA had questions . . . on the dose." (Ex. 11 at 8-9.)

Plaintiff argues that these statements were misleading because the FDA believed "additional dosing studies and data were required." (Pl. Br. at 5.) But "[i]t is well established that there is no affirmative duty to disclose the substance of interim feedback received from the FDA during the pendency of a drug application." *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 584 (S.D.N.Y. 2016). The fact that the FDA may have held a different view about the available data does not make Spectrum's statements misleading. *Tongue v. Sanofi*, 816 F. 3d 199, 214 (2d Cir. 2016) (statements were "not misleading . . . simply because the FDA disagreed with [d]efendants' interpretation of the data"). Reasonable investors in developmental drug companies know "continuous dialogue between the FDA and the proponent of a new drug is the essence of the [new drug] application process" and that "inherent in the nature of a dialogue are differing views" about "the sufficiency of various aspects of the clinical trials." *Id.* at 212 (internal citations omitted). Reasonable investors were not misled.

B. Alignment on Dosage for the Confirmatory Trial (Statement No. 5)

When Spectrum disclosed that it had initiated a confirmatory study with an 8-mg BID dose, Mr. Riga explained that he "believed" Spectrum was "obviously aligned with the FDA on the confirmatory study to go with the 8-milligram BID." (Statement No. 5, Compl. ¶ 128.) Plaintiff argues that this statement was misleading based on negative statements from some FDA staff during the ODAC meeting months later. But the FDA Briefing Book confirms that Spectrum and FDA officials met to "discuss the proposed poziotinib dosing and design of the confirmatory trial" and "agreed that the 8 mg BID regimen as the starting dosage was preferable in the confirmatory trial." (Ex. 1 at 14.) Mr. Riga's statement was accurate.

C. Design of the Confirmatory Study (Statements No. 2, 3, 8, and 9)

When Spectrum discussed the confirmatory study in its Q1 and Q2 2022 earnings announcements, it accurately described the study's design in identical language on both dates:

> A study for poziotinib has been initiated . . . The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) versus 75mg/m2 of docetaxel administered intravenously every three weeks. . . (Statement No. 2, Compl. ¶ 125.)

Spectrum expressly stated that it was discussing the study's "design[ ]." (Ex. 10 at 5; Ex. 11 at 6.) It never said it had enrolled patients in the newly initiated study.

Spectrum's repetition of the same description over several months confirms it was merely describing the study's design. And Spectrum used the same words to describe the study before the ODAC while discussing the fact that no patients had been enrolled. (*See* Ex. 25 at 63:7-16.)[3]

Market participants understood these statements as descriptions of the study's design.

---

[3] The Court can take notice of the ODAC transcript. As Plaintiff acknowledges, "the Complaint cites the full transcript." (Pl. Br. at 10, n.4.)

For example, an analyst from H.C. Wainwright accurately reported that "[t]he company has initiated a confirmatory trial . . . This confirmatory study is designed to enroll 268 patients . . . The design of the study randomizes patients 2:1 . . ." (Ex. 16 at 1.) Similarly, a Jefferies Financial Group Inc. analyst reported to investors that Spectrum "disclosed the confirmatory [Phase III] design for pozi," but said nothing about patients being enrolled in the study.[4] (Ex. 26 at 1 (emphasis added.).) A single analyst's misunderstanding does not mean Spectrum's statements were misleading, particularly given the other analysts who understood the meaning of Spectrum's statements and accurately reported them to the market.

Nor is Plaintiff's claim helped by the fact that Dr. Lebel said in a March 2022 analyst call that it had generally been Spectrum's practice to "discuss design and details of a trial" after enrollment of the first patient. It was similarly Spectrum's practice to expressly announce enrollment of the first patient, (Ex. 24 at 9), and no such announcement was made here. Indeed, Dr. Lebel's statements in the later May 2022 analyst call (in which the alleged misrepresentation was made), when taken in appropriate context, reveal that Dr. Lebel was referring prospectively to anticipated patient enrollment. (Ex. 11 at 6.)

D. Spectrum's Risk Factors (Statement No. 11)

Spectrum's SEC filings disclosed various potential risks to its business, including the risk that "***Clinical trials may fail to demonstrate the safety and efficacy of our drug products, which could prevent or significantly delay obtaining regulatory approval.***" (*See* Ex. 2 at 13.) In its discussion of this risk, Spectrum explained that "[a]ny failure or significant delay in completing clinical trials for [its] drug products" could harm Spectrum's business. (*Id.* at 16.)

[4] The Court may consider these reports. *See Ark. Pub. Emp. Ret. Sys. v. Bristol-Meyers Squibb Co.*, 28 F.4th 343, 352 (2d Cir. 2022) (when "[t]he Complaint refers to analyst reports . . . to argue that [the defendant] misled the market . . . [t]he fact that other reports" expressed different views "is relevant to that argument and properly considered on a motion to dismiss.").

Plaintiff argues that this risk disclosure was misleading because it did not expressly disclose delays to the poziotinib confirmatory study. (Pl. Br. at 45.) Of course, a "purported risk disclosure[ ]" may be misleading "where the company warns" of a risk "when that risk has already materialized." *Rosi v. Aclaris Therapeutics, Inc.*, No. 19-cv-7118 (LJL), 2021 WL 1177505, at *20 (S.D.N.Y. Mar. 29, 2021). But the risk identified "had not materialized." *Id.*

Judge Liman's analysis in *Aclaris Therapeutics* is squarely on point. Aclaris's risk factors warned that the company's drugs "could be subject to post-marketing restrictions . . . and we may be subject to penalties if we fail to comply with regulatory requirements." *Id.* at *19. The plaintiff alleged that those risk disclosures were misleading because, when they were made, the FDA had already twice warned the company that its marketing materials violated FDA regulations. The court rejected this argument because the FDA had not "imposed post-marketing restrictions" and, thus, even if Aclaris knew it had failed to comply with regulatory requirements, the risk identified—that failure to comply with regulatory requirements could subject the company to post-marketing restrictions—"had not materialized." *Id.* at *20. Likewise, the disclosure here concerns not the risk of delays to clinical trials, but the risk that failed clinical trials "could prevent or significantly delay obtaining regulatory approval." (Ex. 2 at 13.) Because that risk had not materialized, Spectrum's risk disclosures were not misleading.

II. THE COMPLAINT FAILS TO PLEAD A STRONG INFERENCE OF SCIENTER

A. Plaintiff's Motive Allegations Fail as a Matter of Law

The Complaint fails to show that the Individual Defendants "benefitted" in any "concrete and personal way from the purported fraud." *ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F. 3d 187, 198 (2d Cir. 2009). To the contrary, Mr. Riga, Dr. Lebel, and Ms. Brennan all substantially increased their stock holdings during the class period. Mr. Riga did not sell a single share; Dr. Lebel sold approximately 2% of his stock

"pursuant to a Rule 10b5-1 trading plan adopted" to "satisfy[ ] tax withholding obligations;" and Ms. Brennan sold less than 1% of hers, also "pursuant to a Rule 10b5-1 trading plan adopted" to "satisfy[ ] tax withholding obligations." (Exs. 22, 23 & 27.)

Name	Holdings (Mar 17, 2022)	Holdings (Sept 22, 2022)	Class Period Stock Sales	Percentage Sold	Proceeds
Thomas J. Riga	568,000	1,213,340	0	0	$0
Francois J. Lebel	255,085	644,790	15,335	2.3%	$14,061.21
Nora E. Brennan	29,277	360,215	3,569	0.99%	$2,801.67

Thus, none of the Defendants obtained a "pecuniary gain . . . at shareholders' expense" from the supposed fraud. *In re N. Telecom Ltd. Secs. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000).

The de minimis stock sales here do not suggest a motive to defraud. Plaintiff's arguments to the contrary ignore the facts and mischaracterize the law. While Plaintiff argues that "Riga's lack of personal stock sales does not negate scienter" (Pl. Br. at 25), "[t]he fact that [some] defendants did not sell . . . undermines" any inference of scienter. *Constr. Laborers Pension Tr. Fund for S. Cal. v. CBS Corp.*, 433 F. Supp. 3d 515, 545 (S.D.N.Y. 2020). While Plaintiff says the Court cannot consider the fact that "the sales were de minimis" (Pl. Br. at 25), courts consistently find sales greater than those alleged here insufficient. *See CBS Corp.*, 433 F. Supp. 3d at 545 (sale of 12.6% of holdings not suspicious); *Patel v. L-3 Commc'ns Holdings Inc.*, No. 14-CV-6038, 2016 WL 1629325, at *11 (S.D.N.Y. Apr. 21, 2016) (sale of "only approximately 16%" was "hardly suspicious"). Finally, the Court may "take judicial notice of [10b5-1] plans and consider them on a motion to dismiss." *CBS Corp.*, 433 F. Supp. 3d at 545.

Nor can Spectrum's sale of stock to finance operations establish motive because Plaintiff "ha[s] not alleged facts indicating that [Spectrum's corporate stock sales] provided a personal, concrete benefit to the Individual Defendants." *L-3 Commc'ns*, 2016 WL 1629325, at *11 (emphasis added). Plaintiff argues that the normal rule should not apply because "Spectrum had

no revenue generating products, and was running out of cash." (Pl. Br. at 24.) As Judge Preska explained in similar circumstances, "[i]t is unclear why this distinction should have any legal import." *Lehmann v. OHR Pharm., Inc.*, 18 Civ. 1284, 2019 WL 4572765, at *6 (S.D.N.Y. Sept. 20, 2019). "The same rationale ungirding the rule" in other cases ("motives common to all corporations cannot be used to establish specific motive") applies to a company running out of cash because "most companies would try to avoid bankruptcy . . . if they were able to do so." *Id.*

Grasping at straws, Plaintiff argues that Spectrum's corporate stock sales "support an inference of corporate scienter." (Pl. Br. at 25.) Nonsense. Corporations do not have "motives." They act only through individual agents. Thus, "[w]here a defendant is a corporation," plaintiffs must "plead[ ] facts that give rise to a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter." *Jackson v. Abernathy*, 960 F. 3d 94, 98 (2d Cir. 2020) (internal citations omitted). Plaintiff fails to do so here.

B. Plaintiff's Recklessness Allegations Fail, Too

Plaintiff's recklessness allegations rest almost entirely on the FDA Briefing Document for the poziotinib ODAC meeting. (Pls. Br. at 22-24.) But an "unfavorable FDA briefing report . . ., released after defendants made the statements now at issue, does not undermine" the conclusion that "defendants honestly believed their description of the data." *In re Sanofi Secs. Litig.*, 87 F. Supp. 3d 510, 546 (S.D.N.Y. 2015). The FDA's statements in the Briefing Book do not contradict Spectrum's statements. (*See* p. 5, *supra*.) While the Briefing Book confirms the FDA raised questions about the proper dose, Spectrum never suggested otherwise. Similarly, while the Briefing Book reflects FDA concerns about the pace of progress on the confirmatory study, the only statements Spectrum ever made on that topic concerned the prospects for achieving substantial enrollment by the November 24, 2022 approval date and nothing in the Briefing Book contradicts those statements. Finally, the Briefing Book confirms Spectrum's

statement about "alignment" with the FDA on dosing for the confirmatory trial. At a minimum, the acknowledgement of "agreement" on dosage for the confirmatory study precludes any finding that Spectrum made its statement recklessly.

Nor does Dr. Lebel's resignation support an inference of scienter. (*See* Compl. ¶¶ 120-121.) As the Second Circuit has explained, "the departure of [a] high-level employee[ ] responsible for the trial [after] the announcement of the trial's failure" is "no reason to doubt the veracity or intent of [the company's] disclosures." *Bristol-Meyers Squibb*, 28 F.4th at 356.

C. Plaintiff Fails to Show Scienter as to Mr. Riga's Forward-Looking Statement (Statement No. 12)

Mr. Riga's statement that Spectrum was "on the cusp" of receiving "FDA approval" was forward-looking. *See Sanofi*, 87 F. Supp. 3d at 535. Thus, to plead scienter, Plaintiff must show Mr. Riga knew the FDA would not approve poziotinib. *See Slayton v. Am. Exp. Co.*, 604 F.3d 758, 773 (2d Cir. 2010) ("the scienter requirement for forward-looking statements is stricter . . . . [L]iability . . . attaches only upon a showing of knowing falsity"). Plaintiff cannot meet this standard, particularly in light of his repeated disavowal of any allegation that "Defendants knew in advance that the Pozi NDA would not be approved."[5] (Pl. Br. at 3 n.2.)

CONCLUSION

The Court should dismiss the Complaint in its entirety.[6]

---

[5] Plaintiff argues "the safe harbor does not apply" because the statement "was not identified as forward-looking." (Pl. Br. at 21.) But "[t]he safe harbor is written in the disjunctive: that is, a defendant is not liable if the forward-looking statement is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false and misleading." *Slayton*, 604 F.3d at 766.

[6] In a footnote, Plaintiff asks for leave to amend if his complaint is dismissed. But "a plaintiff need not be given leave to amend" where he "fails to specify . . . how amendment would cure the pleading deficiencies in its complaint." *Attestor Value Master Fund v. Republic of Argentina*, 940 F.3d 825, 833 (2d Cir. 2019).

Dated: October 6, 2023
New York, New York

BAKER BOTTS L.L.P.

/s/ James J. Beha II
James J. Beha II

Kevin M. Sadler (*pro hac vice*)
1001 Page Mill Road
Building One, Suite 200
Palo Alto, California 94304-1007
(650) 739-7500

Scott D. Powers (*pro hac vice*)
401 South 1st Street
Suite 1300
Austin, Texas 78704-1296
(512) 322-2500

James J. Beha II
John B. Lawrence
Eric DuPont
30 Rockefeller Plaza
New York, New York 10112-4498
(212) 408-2500

Counsel for Defendants Spectrum Pharmaceuticals, Inc., Thomas J. Riga, Francois J. Lebel, and Nora E. Brennan

Christiansen v. Spectrum Pharmaceuticals
Misstatements Alleged in Complaint

Appendix A – Alleged Misstatements in Context

Statement No.	Date	Statement	Source
1	**Mar 17, 2022**	"So you know that the Cohort 2 was dosed at 16 milligrams QD and through Cohort 5 and a number of the work that we've done have produced a pretty healthy body of evidence in the BID setting. So we'll wait and see until the label negotiation part of the discussion with the agency occurs. But we are seeing that 16 QD is certainly a safe and effective dose. And I think over time, we have learned to optimize some of the tolerability and abate some of the AEs [(adverse events)] here with the BID dosage. So I think that will be a key topic when we get to label negotiations with the agency, and we're simply not at that point of the review cycle, which will be coming here shortly." Compl. ¶ 123.	FY 2021 Earnings Call
2	**May 12, 2022**	"A study for poziotinib has been initiated to confirm the clinical benefit seen in Cohort 2, as required for an accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. **Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) versus 75mg/m2 of docetaxel administered intravenously every three weeks. The primary endpoint will be Progression Free Survival.**" Compl. ¶ 125	Q1 Earnings Release
3	**May 12, 2022**	"We believe poziotinib has the potential to be the first to market for this specific indication, an area of great unmet medical need. We now have initiated a randomized confirmatory study following discussion with the FDA and are operat[ing] with a great sense of urgency. Study SPI-POZ-301 or PINNACLE is designed to enroll 268 patients with previously treated non-small cell lung cancer, harboring HER2 exon 20 mutation. **Patients are being randomized 2:1 into this global multicenter study to receive 8-milligram of pozi-administered BID versus 75-milligram per meter square of docetaxel-administered IV every 3 weeks**." Compl. ¶ 126	Q1 Earnings Call

Christiansen v. Spectrum Pharmaceuticals
Misstatements Alleged in Complaint

Statement No.	Date	Statement	Source
4	**May 12, 2022**	"So here's how we're thinking about it. We're looking forward to the opportunity to bring this to an advisory committee and really share the full benefit that pozi could bring in this high area of unmet need. So if you think about even at the acceptance, we had made some statements that the FDA had questions about the status of the confirmatory study as well as questions on the dose. And today, we announced the PINNACLE study which has a dose of 8-milligrams BID, which is different than the 16-milligram QD registrational data. "So it's, for us, very -- it makes a lot of sense. It's very logical that the FDA could have additional questions on dosing and wanting to hear from industry experts on how to bring that issue to resolution. But that's us looking at where we've been, what the discussions have been with the agency, those are two of the issues that certainly could be discussed at ODAC. But as the date gets closer, we will gain more clarity from FDA, and obviously, be prepared to represent the full NDA. So our preparation efforts are -- the last half of your question, they're under – they're actively underway. We think we've got the right team in place to prepare, and are looking forward to the opportunity." Compl. ¶ 130.	Q1 Earnings Call
5	**May 12, 2022**	"So the registrational -- the filing [(the Pozi NDA)] is based on Cohort 2. As you mentioned, the 16 milligrams given QD, and the PMR [post marketing requirement] is at 8-milligrams BID ([the PINNACLE Study)]. So both are 16- milligrams per day. We believe that 16-milligrams QD demonstrated a safe and effective dose for a patient population that needs a solution. I think the subsequent data has given an indication that there could be a more optimal way to reduce some of the on-target toxicities. So I think that the conundrum that you mentioned is likely a topic that FDA would like to hear from industry experts at the ODAC panel. But we believe that **16 QD is a safe and effective dose and obviously aligned with FDA on the confirmatory study to go with the 8-milligram BID**. . . ." Compl. ¶ 128.	Q1 Earnings Call
6	**May 12, 2022**	"We are currently conducting multiple clinical trials for our products . . . The commencement and completion of these clinical trials may be delayed by various factors, including . . . difficulties in identifying and enrolling patients who meet trial eligibility criteria . . . . "Moreover, the commencement and completion of clinical trials may be delayed by many factors that are beyond our control, including: . . . slower than anticipated patient enrollment or our inability to recruit and enroll patients to participate in clinical trials for various reasons . . . ." Compl. ¶ 133.	Q1 2022 10-Q
7	**June 16, 2022**	Spectrum was on "the cusp of not just one, but two FDA approvals with the action dates in the next five months." Compl. ¶ 136.	JMP Life Sciences Conference

Christiansen v. Spectrum Pharmaceuticals
Misstatements Alleged in Complaint

Statement No.	Date	Statement	Source
8	**Aug 11, 2022**	"A study for poziotinib is in progress to confirm the clinical benefit seen in Cohort 2, as required for accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. **Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) verses 75mg/m2 of docetaxel administered intravenously every three weeks.** The primary endpoint is progression free survival." Comp. ¶ 138.	Q2 Earnings Release
9	**Aug 11, 2022**	"Our randomized [confirmatory] study is underway. We have leveraged our team with the extensive experience of PPD, one of the largest international CRO, to conduct the study in as many as 20 countries targeting up to 150 sites. I just returned from the World Lung Cancer meeting, where we had multiple interaction with highly interested international investigators. "We look forward to continuing our active engagement with investigators at the ESMO upcoming meeting. Study 301 or PINNACLE is designed to enroll 268 patients with previously-treated non-small cell lung cancer harboring HER2 exon 20 mutations. **Patients are being randomized 2:1 into this global multicenter study to receive 8 milligram of pozi administered BID versus 75 milligram per meter square of docetaxel administered IV every 3 weeks.** Patient will be evaluated at week 6 and every 6 weeks thereafter. Following progression on docetaxel, patient will be allowed to cross over to be pozi arm. The primary endpoint is progression-free survival with OS, ORR, duration of response and disease control rates, and safety as secondary objectives. This design will provide a power of 95% to test the hypothesis that pozi is superior to docetaxel for a hazard ratio of equal or smaller than 0.5 days using 2 sided logrank test." Compl. ¶ 140.	Q2 Earnings Call
10	**Aug 11, 2022**	"[Defendant Lebel:] So we're -- again, were very active in opening site. But as I'm sure you know, it takes a long time to open sites. We have some site open. **I'm not going to give you numbers today. I'm not going to speak directly to enrollment today.** And so we're moving as fast as we can internationally as well as in North America. So I can't remember -- the second part of your question was what? [Analyst:] Where do you need to be on enrollment to satisfy on FDA's substantial enrollment or PDUFA [date]. [Defendant Lebel:] **So we have discussed directly with the agency if there was a particular threshold that we had to achieve by PDUFA da[te] and the information we got from the [agency is] that this would be a multifactorial judgment that there's not a single number that one has to achieve** and that we believe that on the basis of that discussion is that we have to demonstrate a true active program here that as you know, over the years, the last few years, the number of companies maybe were not quite as serious as they probably had to be, and we believe that we will be able to show unequivocally that we are taking this commitment very seriously and are moving forward as fast as we can. Compl. ¶ 142	Q2 Earnings Call

Christiansen v. Spectrum Pharmaceuticals
Misstatements Alleged in Complaint

Statement No.	Date	Statement	Source
11	**March 18, 2022**	"We are currently conducting multiple clinical trials for our products . . . The commencement and completion of these clinical trials may be delayed by various factors, including . . . difficulties in identifying and enrolling patients who meet trial eligibility criteria . . . . "Moreover, the commencement and completion of clinical trials may be delayed by many factors that are beyond our control, including: . . . slower than anticipated patient enrollment or our inability to recruit and enroll patients to participate in clinical trials for various reasons . . . ." Compl. ¶ 133.	2021 10-K (Annual Report)